Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 10/11/2017 7:32:27 PM
To: Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
Subject: RE: ASAP - For approval -- Press Q Due ASAP Oxitec

Good edits—thank you for jumping in!!
I'm so glad you are in OCSPP!!

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From: Bertrand, Charlotte
Sent: Wednesday, October 11, 2017 2:45 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: RE: ASAP - For approval -- Press Q Due ASAP Oxitec

Thanks Linda – couple of thoughts. Cc'd Rick so he could see my suggestions.

From: Strauss, Linda
Sent: Wednesday, October 11, 2017 2:25 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: ASAP - For approval -- Press Q Due ASAP Oxitec
Importance: High

This is late. Reporter is pining. Rick just approved. I have highlighted the timeframes in yellow.

1. **Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?**
   EPA will regulate GE mosquitoes in the same way the agency regulates other pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives EPA the authority to regulate the distribution, sale, and use of pesticide products to ensure they do not cause unreasonable adverse effects on people or the environment.

   Background:
   More specifically, FIFRA generally requires that, before a pesticide may be sold or distributed in commerce, it must be registered (licensed) based on sufficient scientific data for EPA to conclude that the use of the pesticide will not cause unreasonable adverse effects on people or the environment. FIFRA also gives EPA the authority to issue experimental use permits to allow the testing of a pesticide in the environment for the purpose of generating data to support the registration of the pesticide, and to control the distribution and use of a pesticide post-registration and to monitor its production.

2. **Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?**
   Yes. These products will now be regulated under FIFRA; thus the company must show EPA that their product meets FIFRA established safety standards.

3. **If so, what is the timeline and basic structure of that sort of process?**

Ex. 5 - Deliberative Process

Background:
FIFRA establishes a statutory framework creating timelines within which EPA must make a determination on an application. The timelines applied depends on the type of application submitted by the company.

At this point, EPA has not received an application from Oxitec. However, in general under FIFRA, an applicant typically applies first for an Experimental Use Permit (EUP) to generate the data necessary to

Ex. 5 - Deliberative Process

the EPA's FIFRA Scientific Advisory Panel when the Agency deems such input appropriate.

4. **Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?**

Ex. 5 - Deliberative Process

5. **Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?**
   Over the past few years, EPA has regulated several field trial releases of *Wolbachia* bacteria that are contained within mosquitoes and are being evaluated for control of mosquito populations.
   More information on these trials can be found at:
   - www.epa.gov/pesticides/epa-grants-extension-experimental-use-permit-wolbachia-mosquito
   www.regulations.gov/docket?D=EPA-HQ-OPP-2017-0392

From: StClair, Christie
Sent: Friday, October 06, 2017 2:08 PM
To: Hanley, Mary <Hanley.Mary@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Strauss, Linda <Strauss.Linda@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>
Subject: The Scientist (DDL COB today): Mosquitos

Hi Mary and Cheryl,

Is there any possibility of answering these today?

Thanks,
Christie

Abby Olena
The Scientist
Deadline is 5pm Monday, so essentially COB today.

1. Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?

2. Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?

3. If so, what is the timeline and basic structure of that sort of process?

4. Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?

5. Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?